K111215
P1/4

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510(k) Summary

Submission Date:	29 April 2011
Submitter:	Ascom (Sweden) AB P.O. Box 8783 SE-402 76 Göteborg Sweden
Submitter and Official Contact:	Ms. Tania Ottebrink Manager of Product Configuration & Conformity P.O. Box 8783 SE-402 76 Göteborg Sweden Phone: +46 31 55 93 00 Email : Tania.Ottebrink@ascom.se
Manufacturing Site:	Ascom (Sweden) AB Grimbodalen 2 SE-417 49 Göteborg Sweden
Trade Name:	Ascom Mobile Monitoring Gateway (MMG)
Common Name:	Network and Communication Middleware
Classification Name:	System, Network And Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:	*Ascom Model*	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
	Ascom Mobile Monitoring Gateway (MMG)	K103634	Ascom Cardiomax

Device Description: The Ascom Mobile Monitoring Gateway (MMG) is an on-site messaging integration solution which forwards patient monitor status and alarm information to the user via display devices provided by Ascom or third-party mobile device companies. Users receive interactive, time-critical information from patient monitoring devices directly via their display devices as text, alarms or data. The Ascom MMG allows users to be aware of their patients' status and alarm conditions when they are away from the patient and patient monitoring system.

The Ascom MMG connects to the information sources through wired Ethernet connections which are part of the customer's infrastructure. The Ascom MMG software acquires patient data from patient monitoring devices. The user configures the Ascom MMG to determine which information, including alarm notifications, is delivered to which users. The Ascom MMG then formats the data for wireless delivery to the display devices.

All messaging activities are recorded in the Ascom Unite Connectivity Manager providing real-time activity logging for audit trail records and reporting. The Ascom MMG hardware consists of small, embedded network appliances, and application-specific software. The Ascom MMG delivers near real-time text messaging alerts and information to text-capable display devices.

The Ascom Mobile Monitoring Gateway operates on a wireless communications system platform. The communication platform uses DECT (Digital Enhanced Cordless Telecommunications), WiFi and Paging technology. The Ascom MMG combined with a wireless communication system, is part of an Ascom end-to-end solution designed to provide all the components necessary to optimize work flow, including display devices, gateways and device management.

Intended Use:	The Ascom Mobile Monitoring Gateway (MMG) is intended to interface with the GE Healthcare patient monitoring network and the Ascom Messaging System, in order to provide a secondary means of automated visual and/or audible annunciating and displaying of patient alarm information to healthcare professionals, via display devices. The MMG does not alter the behavior of the monitoring system. Neither is it intended to replace or alter the primary alarm function on the patient monitor. The MMG is not intended to be used for diagnostic purposes. The MMG is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the healthcare facility and the display devices used. The MMG software is installed on specified hardware located in a computer hall or similar, where the MMG can't come into physical contact with patients.
Technology Comparison:	The Ascom Mobile Monitoring Gateway (MMG) employs the same or similar technological characteristics as the predicate device.
Performance Testing:	
Sterilization and Shelf-Life	The Ascom Mobile Monitoring Gateway (MMG) is not provided sterile and is not intended to be sterilized by the user. Additionally, the Ascom Mobile Monitoring Gateway (MMG) does not have a shelf-life. Therefore, this section is not applicable.
Biocompatibility	The Ascom Mobile Monitoring Gateway (MMG) does not directly or indirectly contact the patient. Therefore, this section is not applicable.
Software Testing	Software for the Ascom Mobile Monitoring Gateway (MMG) was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Ascom Mobile Monitoring Gateway (MMG) complies with its predetermined specifications.
Electrical Safety	The Ascom Mobile Monitoring Gateway (MMG) was tested for electrical safety in accordance with applicable Standards. Test results indicated that the Ascom Mobile Monitoring Gateway (MMG) complies with its predetermined specifications and with the applicable standards.

Electromagnetic Compatibility Testing	The Ascom Mobile Monitoring Gateway (MMG) was tested for EMC in accordance with applicable Standards. Test results indicated that the Ascom Mobile Monitoring Gateway (MMG) complies with its predetermined specifications and with the applicable standards.
Performance Testing – Bench	The Ascom Mobile Monitoring Gateway (MMG) was tested for performance in accordance with predetermined specifications and applicable Standards. Test results indicated that the Ascom Mobile Monitoring Gateway (MMG) complies with its predetermined specifications.
Conclusion	Based upon a comparison with predicate devices and testing results, the Ascom Mobile Monitoring Gateway (MMG) is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Ascom (Sweeden) AB – Wireless Solutions
c/o Ms. Tamia Ottebrink
Manager of Product Configuration & Conformity
Grimbodalen 2, P.O. Box 8783
Goteborg
Sweden SE-402 76

Re: K111215
Trade/Device Name: Ascom Mobile Monitoring Gateway (MMG)
Regulatory Number: 21 CFR 870.2300
Regulation Name: Network and Communication, Physiological Monitors Systems
Regulatory Class: II (two)
Product Code: MSX
Dated: April 29, 2011
Received: May 2, 2011

Dear Ms. Ottebrink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111215

Indications for Use

510(k) Number: K

Device Name: Ascom Mobile Monitoring Gateway (MMG)

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The MMG does not alter the behaviour of the monitoring system. Neither is it intended to replace or alter the primary alarm function on the patient monitor. The MMG is not intended to be used for diagnostic purposes.

The MMG is intended for use by professional clinical personnel and relies on proper use and operation of both the communication infrastructure in place at the healthcare facility and the display devices used.

The MMG software is installed on specified hardware located in a computer hall or similar, where the MMG can't come into physical contact with patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111215